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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,598	09/10/2003	Miri Seiberg	JBP-430-CIP1	5368
27777	7590	06/28/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,598

Applicant(s)

SEIBERG ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 1-10 and 63 are pending.

Claims 11-62 are cancelled.

Response to Amendment

The response filed **March 31, 2006** presents remarks and arguments to the office action mailed **January 05, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Rejection Claim Rejections - 35 USC § 112-First Paragraph

Applicant traverses with regards to the rejection made under 35 U.S.C. 112-first paragraph, that the claim does not describe all nondenatured botanical extract but rather relates to nondenatured botanical extracts having trypsin-inhibiting activity.

In response, the scope of enablement question still remains, specifically with regards to items 1-3 of the scope of enablement cited in the previous action. The phrase nondenatured plant extract with trypsin-inhibiting activity as shown poison ivy also do contain trypsin inhibitor, but cannot be used for the treatment of skin disease instead an adverse reaction is seen (see enclosed reference cited as of interest Hegarty et al. page 40 section b).

In order to overcome this rejection, Applicant needs to recite the disclosure in of the specific non-denatured botanic extract in generality into the claim. As it stands claim 1 is very broad and it encompasses a variety of nondenatured botanic extracts that have trypsin inhibitor activity including poison ivy extract.

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Applicant's arguments have been fully considered but they are not persuasive.

And the rejection is hereby maintained in part.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

I. Claims 1-10 and 63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for botanical families of leguminosae, solanaceae, gramineae, and cucurbitaceae, does not reasonably provide enablement for most nondenatured botanical extract. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered.

Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, 7) the relative skill of those skilled in the art and 8) the quantity of experimentation needed.

1) The nature of the invention: The method of use claims are drawn to topically administering a nondenatured botanical extract but in view of the report Botanical.com

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A modern Herbal: indicates (see page 1, 2nd paragraph) that the sap of poison Ivy is extremely poisonous (thus sap is nondenatured), which does not support applicants' claims in treating skin conditions with nondenatured botanical extract.

2) The state of the prior art: The report (see page 1 Botanical.com A modern Herbal) suggests that not every nondenatured botanical extracts are used for the treatment of skin conditions and in order to use a wide representative of nondenatured botanical extracts requires an undue amount of research to successfully attain that goal.

3) The predictability or lack thereof in the art: On page 23 of applicants' specification lines 1-30 did not show total treatment with nondenatured botanical extracts.

Thus, factors such as "discussed above", have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

II. The rejection under 112-first paragraph with regards to enablement issue has been withdrawn. Applicants' argument has been fully considered and is persuasive.

New Claim 112-first rejection

Claims 1-10 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to

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practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

In particular, Applicant has not provided a description of the structure of a representative number of compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds recited in claims 1-10 and 63. In other words, the Applicant has not described with sufficient clarity a medicament for treating acne with every synthetic retinoid available or every nondenatured botanical extracts for example.

No claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
6/13/06


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER